

1653 IDS
AS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:) Art Unit:
GRØFTE, Thørbjørn) Examiner:
Serial No.: 09/928,832) Washington, D.C. TECH CENTER 1600/2900
Filed: August 14, 2001) December 19, 2001
Art: TREATMENT OF ACUTE AND...) Docket No.: GRØFTE=1A

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INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner of Patents
and Trademarks
Washington, D.C. 20231

S i r :

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:

[] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application. See 37 CFR 1.97(b).

[X] B. before the mailing date of a first office action on the merits. See 37 CFR 1.97(b).

[] C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "ii"

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below). See 37 CFR 1.97(c).

[] i. Counsel certifies that, upon information and belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

[] ii. A check for the fee set forth in 1.17(p), presently believed to be \$180, is enclosed (check no. _____).

[] D. after (A), (B) and (C) above, but before payment of the issue fee. Applicant petitions under 37 C.F.R. 1.97(d) for consideration of this IDS. A check for the fee set forth in 1.17(i)(1), presently believed to be \$130 is enclosed (check no. _____). Counsel certifies that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

[] E. As a submission in accordance with the transitional procedure for limited examination after final rejection pursuant to 37 CFR §1.129(a). Pursuant to MPEP §706.07(g), page 700-46, col. 2 (February 2000), this IDS is treated as if filed with a period set forth in 37 CFR §1.97(b)

and considered without the petition and petition fee required by 1.97(d).

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO-1449) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document is attached, except as explained below.

[X] While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is "encouraged"). Counsel has used a list provided to him by Applicants, and not transferred the information to a PTO-1449, to avoid the risk of any inadvertent error in transferring the information.

[] A. Documents _____ are deemed substantially cumulative to documents _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.

[] B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

[insert serial number/filing date]

Applicants identify these documents by attaching hereto copies of the form PTO-892s and PTO-1449s from the files of the prior applications or a fresh PTO-1449 listing these documents, and request that they be considered and made of record in accordance

with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application. If copies of any of these documents cannot be found in the files of the prior applications, the Examiner is requested to so notify counsel before taking action in this case, so replacement copies can be submitted. While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is "encouraged") and no prohibition on submitting a copy of a form PTO-1449 or form PTO-892 from a prior case. Indeed, the re-use of such forms is desirable as it avoids error in transferring the information, and evidences that the reference was considered in a prior application. A previously accepted PTO-1449, or an examiner-prepared PTO-892, necessarily complies with §1.98(b).

[] 3. Documents _____ are not in the English language. In accordance with 1.98(c), Applicants state:

[] documents _____ already contain an English language abstract, summary or claim set.

[] a publicly available abstract is attached to each of documents _____, and the source of each abstract is indicated thereon.

[] documents _____ are patents or published patent applications for which counterpart English language patents or patent applications exist, and are enclosed, as follows:

| <u>Foreign Lang. Doc.#</u> | <u>English Lang. Doc.#</u> |
|----------------------------|----------------------------|
| [insert] | [insert] |

[] applicants have prepared an English translation of

at least the pertinent portions of documents _____, and copies are attached.

[] A concise explanation of the relevance of documents _____ is found in the attached search report from the _____ Patent Office (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).

[] A concise explanation of the relevance of documents _____ is set forth as follows:
[Insert concise explanation of relevance]

4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

5. Other information being provided for the examiner's consideration follows:

[insert other information]

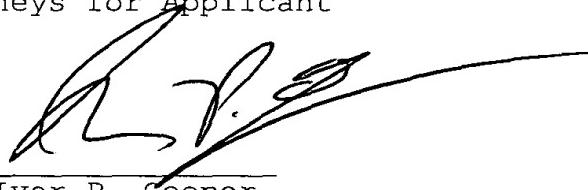
6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

7. The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035.

Respectfully submitted,

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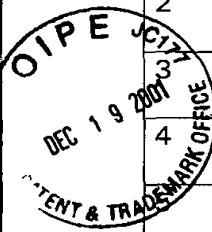
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Information disclosure statement

Grøfte et al., filed 14. August, 2001

Your ref.: GRØFTE=1A; Our ref.: P 479 DK00

| 1 | US 6,034,059 3/7/2000 | Fryklund et al., Treatment of catabolic states using authentic IGF-1 and hypocaloric amount of nutrients. |
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| 2 | WO 99/24062 5/20/1999 | Shirley et al., Novel IGF-I composition and its use. |
| 3 | US 5,948,757 9/7/1999 | Sommer et al., High dose IGF-1 therapy. |
| 4 | US 5,723,441 3/3/1998 | Higley et al., Method of treating renal disease by administering IGF-I and IGFBP-3. |
| | US 5,681,814 10/28/1997 | Clark et al., Formulated IGF-I composition. |
| 6 | US 5,273,961 12/28/1993 | Clark et al., Method of prophylaxis of acute renal failure. |
| 7 | US 5,187,151 2/16/1993 | Clark et al., Use of binding protein with IGF-I as an anabolic growth promoting agent. |
| 8 | US 6,071,880 6/6/2000 | Acott et al., Use of IGF-I for the treatment of renal insufficiencies, steroid toxicity and related indications. |
| 9 | US 5,492,891 2/20/1996 - | Skakkebæk et al., Method for treatment of patients with chronic liver disease. |
| 10 | US 5,068,224 11/26/1991 | Fryklund et al., Method for improving regeneration of transfected peripheral nerves using IGF-1. |
| 11 | US 5,434,134 7/18/1995 | Gluckman et al., Use of human IGF-1 to treat cardiac disorders. |
| 12 | US 5,466,670 11/11/1995 | Dunger et al., Use of IGF-1. |
| 13 | US 5,756,463 5/26/1998 | Arrhénius-Nyberg et al., Use of insulin and IGF-1. |
| 14 | WO 90/00569 1/25/1990 | Baxter et al., Acid-labile subunit (ALS) of insulin-like-growth factor (IGF) binding protein complex. |
| 15 | | Møller et al., The acid-labile subunit of the ternary insulin-like growth factor complex in cirrhosis: relation to liver dysfunction, <i>Journal of Hepatology</i> , vol. 32, 2000, 441-446 |
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| 18 | | Caregaro et al., Nutritional and prognostic significance of insulin-like growth factor 1 in patients with liver cirrhosis, <i>Nutrition</i> , vol. 13, 1997, 185-190 |



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| 19 | | <u>Castilla-Cortazar et al.</u> , Insulin-like growth factor-I reverts testicular atrophy in rats with advanced cirrhosis, <i>Hepatology</i> , vol. 31, 2000, 593-599 |
| 20 | | <u>Castilla-Cortazar et al.</u> , Impaired intestinal sugar transport in cirrhotic rats: correction by low doses of insulin-like growth factor I, <i>Gastroenterology</i> , vol. 113, 1997, 1180-1187 |
| 21 | | <u>Donaghy et al.</u> , Growth hormone, insulinlike growth factor-1 and insulinlike growth factor binding proteins 1 and 3 in chronic liver disease, <i>Hepatology</i> , vol. 21, 1995, 680-688 |
| 22 |  | <u>Friedman & Keeffe</u> , Handbook of liverdisease, Publishers: <i>Churchill Livingstone</i> , 1998, 85-133 |
| 23 | | <u>Kondrup et al.</u> , Effect of long-term refeeding on protein metabolism in patients with cirrhosis of the liver, <i>British Journal of Nutrition</i> , vol. 77, 1997, 197-212 |
| 24 | | <u>Kratzsch et al.</u> , Regulation of growth hormone (GH), insulin-like growth factor (IGF)I, IGF binding proteins -1, -2, -3 and GH binding protein during progression of liver cirrhosis, <i>Exp Clin Endocrinol</i> , vol. 103, 1995, 285-291 |
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| 28 | | <u>Shmueli et al.</u> , High insulin-like growth factor binding protein 1 levels in cirrhosis: link with insulin resistance, <i>Hepatology</i> , vol. 14, 1996, 127-133 |
| 29 | | <u>Grøfte et al.</u> , Insulin-like growth factor-I improves glucose metabolism and hepatic amino acid-N conversion in patients with liver cirrhosis, <i>Growth hormone & IGF research</i> , vol. 10, 2000, page 134 |
| 30 | | <u>Grøfte et al.</u> , Growth hormone (GH) treatment for 1 week results in marked insulin resistance despite concomitant treatment with insulin-like growth factor-I (IGF-I) in normal man, <i>Clinical Nutrition</i> , vol. 19, 2000, page 32 |
| 31 | | <u>Blomsma et al.</u> , Insulin-like growth factor-I in liver cirrhosis, <i>Journal of Hepatology</i> , vol. 27, 1997, 1133-1138 |
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| 33 | US 5,783,559 7/21/1998 | <u>Florin-Robertsson et al.</u> , Solution containing IGF-1. |